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7 SPECIAL MASTER

8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA

E-filing

10 RENEE CONTRATTO, on behalf of
11 herself and the general public,

12 Plaintiff(s),

13 vs.

14
15 ETHICON, INC. et al., (dba
16 GYNECARE WORLDWIDE), a
17 New Jersey Corporation; JOHNSON
18 & JOHNSON, a New Jersey
19 Corporation; LIFECOREE
20 BIOMEDICAL, INC., a Florida
21 Corporation; and DOES 1-25,

22 Defendant(s).

CASE #: C03-3804 MJJ (BZ)
JAMS Ref#: 1100043994

SPECIAL MASTER'S ORDER NO.
5: LIFECORE'S MOTION TO
MAINTAIN CONFIDENTIALITY
OF DOCUMENTS AND
DEPOSITION TESTIMONY (Hrg.
8/24/05)

23 On August 24, 2005, Lifecore's motion to maintain the confidentiality of documents
24 produced and deposition testimony in this case was heard by Special Master Martin Quinn.
25 Counsel for all parties were present in person or by telephone. Having considered all the
26 argument submitted by the parties and reviewed all the documents in question, the Special
27 Master orders as follows.

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I. Relevant Facts

On February 9, 2004, Judge Jenkins signed a stipulated protective order that allowed defendants to designate documents as confidential. Defendants Lifecore and Ethicon designated virtually all the documents they produced ("all but a few hundred out of three to four hundred thousand documents," according to Judge Zimmerman's 2/7/05 Order). Plaintiff duly objected, and Lifecore and Ethicon moved for an order to uphold the confidential designation of 13 disputed documents. In an Order Denying Defendants' Motion to Uphold Confidential Designation of Documents, dated 2/7/05, Judge Zimmerman found that none of the 13 documents was entitled to confidentiality protection under FRCP 26(c) either as a "trade secret" or as "confidential research, development, or commercial information." Judge Zimmerman based his Order on both (1) the absence of any detailed evidence to show that the information was truly secret and that its disclosure would harm Lifecore, and (2) his own inspection of the documents.

In light of the 2/7/05 Order, the parties have tried to reach agreement on which of the remaining documents should remain confidential. While they have been partially successful, disputes still remain. By this motion, Lifecore once again asks the court to endorse its confidentiality designations of about 25 documents and five groups of deposition testimony. Plaintiff argues that, apart from limited redactions of portions of some of the documents that contain numeric details of manufacturing formulas, none of the documents or testimony is entitled to be designated confidential.

II. Analysis

A. General Principles

The Special Master approaches the present motion guided by the analysis and conclusions of Judge Zimmerman's 2/7/05 Order that found that very similar documents were not confidential. However, the Special Master is also mindful that Lifecore has submitted very significantly more detailed evidence in support of confidentiality than was before Judge Zimmerman. Therefore, while adhering to the legal principles in the 2/7/05 Order, the Special

1 Master has reviewed carefully and relied upon the declaration of James Hall, Lifecore's Director
2 of Manufacturing and Operations since 2001, and the evidence attached to the two declarations
3 of Thomas Watson, one of Lifecore's counsel.

4 All but a few of the documents and testimony relate to two periods of research and
5 investigation of "globules", or "particulates," that seemed to form in Intergel during the
6 manufacturing process. Plaintiff alleges that her injuries were caused by Intergel "contaminated
7 with small particulates of ferric or iron hydroxide." [Watson decl., Exh. F] The first period of
8 investigation was in 1996-1998 when the product was being readied for market; the second was
9 in 2003 after Intergel had been removed from the market.

10 An important consideration in evaluating this motion is that Judge Zimmerman found that
11 a 6/19/03 Lifecore memo about the second globule investigation [Talley decl., Exh. 3] was not
12 confidential. His 2/7/05 Order states, at p. 11, that the document does "not appear to contain
13 secret information, nor does it appear that the public disclosure of the documents would harm
14 defendants. ... I have determined that the document only generally summarizes past research
15 performed on the product and does not reveal proprietary formulas for the product or contain
16 confidential research procedures." The 6/19/03 memo summarizes in considerable detail
17 Lifecore's preliminary findings and conclusions, the test procedures employed, and the
18 corrective actions Lifecore was contemplating. Given that this document is already public, it
19 makes little sense to keep documents confidential that contain less specific information about the
20 globule investigation.

21 Notwithstanding defendants' arguments, the Special Master concludes that the mere
22 existence and the general parameters of these two investigations are not entitled to
23 confidentiality under Rule 26 (c). The fact that a pharmaceutical company is investigating the
24 efficacy of its product, at least under these circumstances, is neither a trade secret nor
25 confidential commercial information. Nor is non-specific information about the scope or
26 conclusions of such investigations entitled to confidentiality. On the contrary, Lifecore is
27 entitled to protect specific information about those investigations that would give a competitor a
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1 road map of how to avoid similar manufacturing problems, or would reveal unique, non-obvious
2 features of Intergel's makeup or the process for manufacturing it. News media recently reported
3 that known problems with a heart defibrillator, that caused short circuits and apparently one
4 death, were not made public because of confidentiality concerns. This incident illustrates the
5 public interest in prompt disclosure when manufacturers investigate problems with their medical
6 devices -- in the absence of clear danger of competitive harm.

7 B. The Disputed Documents

8 With reference to the tabbed Exhibits to the Hall declaration supplied by counsel for
9 Lifecore, the Special Master finds that the designated portions of the following documents, and
10 related deposition testimony, may not properly be designated as Confidential: Tabs A, B, C, D,
11 E, G, H, I, K, N, O, P, S, T, U, W and Y. All these documents contain only very general
12 descriptions of investigations, research or processes. Many of them are close to 10 years old.
13 Much of the material is obvious (e.g., that Lifecore would consider animal testing). Some of
14 them are so similar to the 6/19/03 memorandum that Judge Zimmerman ordered disclosed that
15 there is no further basis to keep these documents confidential.

16 The Special Master finds that all or part of the designated portions of the following
17 documents may properly be designated as Confidential: Tabs F, J, L, M, Q, R and X.
18 Deposition testimony related directly to the confidential portions of these documents may also be
19 designated as Confidential.

20 Tab F: 8/18/03 Investigation Summary. The Root Cause Analysis (60868-60871) and
21 the Historical Data and Attachments (60873-60887) may be designated Confidential because
22 they contain specific information about product makeup, manufacturing processes and research
23 procedures. The remainder of the designated portion may not be designated Confidential.

24 Tab J: Portion of PMA re Stability Studies, 11/24/98. The entire designated portion may
25 be designated Confidential. It contains specific information about storage procedures and
26 specifications for the product that could be of competitive value if disclosed. There is no
27 compelling public interest in disclosure.
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1 Tab L: PMA Amendment, 9/99. Pages 7148, 7162 and 7163 may be designated
2 Confidential since they contain specific information about product specifications and test
3 procedures. The rest of the designated portion must be disclosed.

4 Tab M: Stability Study, 2/8/00. The entire designated portion may be designated
5 Confidential because it contains details of protocols and research results concerning the stability
6 of the product. There is no compelling public interest in disclosure.

7 Tab Q: Emails and related documents re Intergel globule investigation. The 3/4/03 email
8 (01372) may not be designated Confidential. The remaining designated portions of the
9 documents may be designated Confidential, since they discuss specific procedures and results of
10 the investigation at a level of detail that could be of competitive value if disclosed.

11 Tab R: 3/26/03 Background Investigation and Quality Audit, and 8/12/03 memo re
12 investigation re globules. Pages BAC 013746 (the first page of the document), and the 8/12/03
13 memo (BAC 005547) may not be designated Confidential. The remaining designated portions of
14 the document may be designated confidential since they discuss procedures and results of the
15 quality audit at a level of detail that could be of competitive value if disclosed.

16 Tab X: Vital Pharma Quality Control Procedure, 1/4/03. The entire designated portion
17 of the document may be designated Confidential, since it contains specific manufacturing
18 procedures that could be of comparative value if disclosed. There is no compelling public
19 interest in disclosure.

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21 C. The Disputed Deposition Testimony Not Related to a Document

22 The designated portions of the testimony of Douglas Johns, and of pages 22-37 of the
23 testimony of Jackie Kieser, may be designated Confidential. The remainder of the Kieser
24 deposition, and the entirety of the Bracke, diZerega and Keyport depositions may not be
25 designated Confidential.

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III. Order

Accordingly, good cause appearing, it is ORDERED that defendants' motion is
GRANTED IN PART:

1. Defendants may designate as Confidential the portions of the documents and deposition testimony identified above. All remaining portions of the disputed documents at issue on this motion shall not be subject to confidentiality under the protective order entered in this case.

2. The JAMS charges for the Special Master to hear this motion shall be paid 50% by Lifecore and 50% by plaintiff.

Dated: September 13, 2005


Martin Quinn, Special Master